

Group Art Unit 188 Examiners J. Witz &

D. W. Robinson

PATENT

IN THE UNITED STATES PATENT & TRADEMARK OFFICE

In re application of

LAWRENCE A. JOHNSON

Serial No. 07/692,958 CENTED

Filed April 26, 1991

The Honorable

The Commissioner

The Commissioner of Patents & Trademarks

Sir:

PETITION UNDER 37 CFR 1.313(a) WITHDRAWAL FROM ISSUE

Applicant respectfully requests that the above-identified application be withdrawn from issue. THE COMMISSIONER IS AUTHORIZED TO CHARGE DEPOSIT ACCOUNT 01-0455 IN THE AMOUNT OF \$130.00 FOR THE REQUIRED FEE UNDER 37 CFR 1.17(i)(1).

The Notice of Allowability in the above-identified application was received on March 30, 1992, and the issue fee was promptly paid on April 1. Withdrawal from issue is requested for the following reasons:

> I hereby certify that this correspondence is being deposited with the U.S. Postal Service as first class mail in an envelope addressed to: Commissioner of Patents and Trademarks Washington, D.C. 20231, on (Date of Deposit)

Curtis P. Ribando Name of Applicant, assignee, or

Signature

Date of Signature

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In the Examiner's Statement of Reasons for Allowance, the Examiner stated:

The Declarations filed January 13, 1992 and May 30, 1991 combined serve to indicate that the sorting of intact sperm with tails combined with the staining at a temperature of $30-39^{\circ}\text{C}$ patentably the [sic] defines over the prior art which shows sorting of tailess sperm heads having been stained at room temperature.

On April 14, 1992, the undersigned received a copy of the Supplementary European Search Report from counsel handling matters relating to the foreign patent prosecution. By virtue of that report, applicant's counsel first became aware of the Adair reference cited on the PTO-1449, submitted herewith. Similar to the applicant's invention, Adair relates to separating sperm into X and Y components so that the sex of offspring can be predetermined. The reference relies upon the principal of differential DNA staining of X and Y sperm cells with a fluorescent dye and separating based on the difference in flourescence. Of particular significance is the passage on page 5, lines 24-29, wherein it is stated:

The semen is then stored in a water bath at approximately the body temperature of the animal. This is between about 35°C and about 38.5°C, but is usually about 37°C. If the temperature is substantially above or below this range, sperm mobility will decrease and the survival rate of the sperm will decrease below acceptable limits.

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At first blush, the temperature treatment of Adair could be construed as suggesting the applicant's point of novelty. Therefore, applicant and the undersigned wish to fulfill their duty of disclosure under 37 CFR 1.156 by submitting this reference for consideration by the Examiner. Applicant also wishes to resolve herein any potential issues of patentability which could be raised by this reference. Stated below are the reasons why Adair, taken alone or in combination with the art of record, fails to teach or suggest the claimed invention.

Though Adair makes it clear that the collected semen should be stored at the stated mammalian body temperature range prior to staining, nowhere is it stated that the semen should be held at that temperature during the staining. As an alternative to storing the semen at body temperature, the sperm cells can be separated out of the semen fluid and diluted in a suitable saline solution (presumably at room temperature; see page 3, lines 25-28). There is no clear suggestion by Adair that the temperature range claimed by the applicant or that taught by Adair would be instrumental in facilitating absorption of the dye. The saline solution alternative would support the supposition that Adair failed to recognize any correlation between the holding temperature and successful dyeing of the cells. In fact, Adair relies upon a completely different method to

promote dye uptake. As noted on page 5, lines 30-34, and on page 6, lines 15, a cell membrane diffusion material must be used for this purpose for most mammalian sperm. The use of the cell diffusion material is further discussed on page 2, lines 11-20, of the reference.

The Examiner will note that the passage from Adair reproduced above speaks to effects of temperature on the viability of the sperm, but makes no mention of the effects of time. The implication of this passage and that on page 3, lines 25-28, is that the sperm cells will remain viable indefinitely at the designated temperatures. The person in the art of the biological sciences will recognize that many cells, microorganisms, enzymes, and the like are long-lived within the range of 35°-38.5° C. But as the data and statements of record in the application will show, sperm cells quickly lose viability at these temperatures. Adair fails to appreciate this fact and also fails to take any precautions to avoid sperm devitalization. No actual viability data is presented. In contrast, all the applicant's allowed claims require that the incubation take place "for a period of time sufficiently long for staining to take place uniformly but sufficiently short to preserve viability of the sperm." Adair's only concern about sperm viability relates to using too high of a diffusion material concentration (page 6, lines 11-15) or too high of a dye concentration (page 6, lines 28-30).

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Finally Adair is silent regarding whether or not his method preserves the integrity of the sperm cells and whether or not his process is operable for separating intact sperm with tails. This reference is marked by many of the same deficiencies as the art previously of record. Upon careful review, it becomes readily apparent that Adair neither anticipates nor renders obvious the claimed invention.

For the above-stated reasons, the Examiner is asked to reaffirm the patentability of Claims 9-34 and to pass the case to issue.

Respectfully submitted,

Curtis P. Ribando, Agent of Record

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Enclosures:

Supplemental List of Prior Art Cited by Applicant

Reference AL